CLAIMS

1. A substantially pure nucleic acid molecule comprising: (i) a nucleic acid sequence encoding recombinant human alpha-fetoprotein (rHuAFP), (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by milk-producing cells into the milk of a mammal.

2. A substantially pure nucleic acid molecule comprising: (i) a nucleic acid sequence encoding recombinant human alpha-fetoprotein (rHuAFP), (ii) a urine-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by urine-producing cells into the urine of a mammal.

3. A non-human transgenic mammal that expresses recombinant human alpha-fetoprotein (rHuAFP) in its milk, wherein milk-producing cells of said mammal contain a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by milk-producing cells into the milk of a mammal.

4. A non-human transgenic mammal that expresses recombinant human alpha-fetoprotein (rHuAFP) in its urine, wherein urine-producing cells of said mammal contain a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a urine-specific promoter, said promoter being operably

linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by urine-producing cells into the urine of an animal.

5. The non-human transgenic mammal of claim 1 or 2, wherein the mammal is a goat, a cow, a sheep, or a pig.

6. Non-human mammal's milk comprising recombinant human alpha-fetoprotein (rHuAFP).

7. The milk of claim 6, wherein the rHuAFP is soluble and is produced by a non-human transgenic mammal whose milk-producing cells express a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by said milk-producing cells into the milk of said mammal.

8. Non-human mammal's urine comprising recombinant human alpha-fetoprotein (rHuAFP).

9. The urine of claim 8, wherein the rHuAFP is soluble and is produced by a non-human transgenic mammal whose urine-producing cells express a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a urine-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by said urine-producing cells into the urine of said mammal.

10. A method of producing recombinant human alpha-fetoprotein (rHuAFP) that is secreted in the milk of a mammal, said method comprising the steps of:

(a) providing a cell transfected with a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by a milk-producing cell, wherein said milk-producing cell is derived from said transfected cell;

(b) growing said cell to produce a mammal comprising milk-producing cells that express and secrete said rHuAFP into said milk; and

(c) collecting said milk containing said rHuAFP from said mammal.

11. The method of claim 10, wherein said rHuAFP is purified from said milk.

12. A method of producing recombinant human alpha-fetoprotein (rHuAFP) that is secreted in the urine of a mammal, said method comprising the steps of:

(a) providing a cell transfected with a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a urine-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by a urine-producing cell, wherein said urine-producing cell is derived from said transfected cell;

(b) growing said cell to produce a mammal comprising urine-producing cells that express and secrete said rHuAFP into said urine; and

(c) collecting said urine containing said rHuAFP from said mammal.

13. The method of claim 12, wherein said rHuAFP is purified from said urine.

14. A method of treating a patient in need of recombinant human alpha-fetoprotein (rHuAFP), said method comprising administering to said patient a therapeutically-effective amount of non-human mammal's milk comprising recombinant human alpha-fetoprotein (rHuAFP).

15. The method of claim 14, wherein said rHuAFP is produced by a non-human transgenic mammal whose milk-producing cells contain a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by milk-producing cells into the milk of said mammal.

16. A method of treating a patient in need of recombinant human alpha-fetoprotein (rHuAFP), said method comprising administering to said patient a therapeutically-effective amount of recombinant human alpha-fetoprotein (rHuAFP) purified from a non-human mammal's urine.

17. The method of claim 16, wherein said rHuAFP is produced by a non-human transgenic mammal whose urine-producing cells contain a transgene that comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a urine-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by urine-producing cells into the urine of said mammal.

18. The method of claim 14 or 16, wherein said method is for the treatment of cancer.

19. The method of claim 14 or 16, wherein said method is for suppressing the immune system of a patient in need thereof.

20. The method of claim 14 or 16, wherein said method is for inducing proliferation of bone marrow cells in a patient in need thereof.